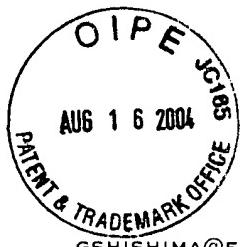


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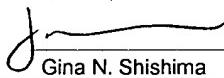
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Date

 Gina N. Shishima

## MS AMENDMENT

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/791,692 entitled "METHODS AND COMPOSITIONS INVOLVING MDA-7" – Sunil Chada et al.*  
*Our reference: INGN:105US*  
*U.T. Ref. MDA03-090*

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references A1-A38, B1-B8 and C1-C132.

No fees are believed to be due in connection with the filing of this Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INGN:105US.

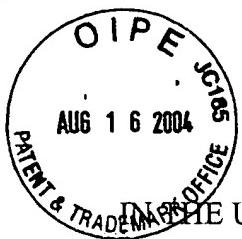
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Respectfully submitted,

  
 Gina N. Shishima  
 Reg. No. 45,104

GNS/kmv  
 Encl.: as noted

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PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Sunil Chada *et al.*

Serial No.: 10/791,692

Filed: March 2, 2004

For: METHODS AND COMPOSITIONS  
INVOLVING MDA-7

Group Art Unit: 1645

Examiner: Unknown

Atty. Dkt. No.: INGN:105US

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Date

Gina N. Shishima

INFORMATION DISCLOSURE STATEMENT

**MS AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

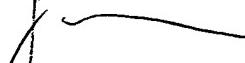
an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INGN:105US.

This application is related by inventorship to co-pending U.S. Application No. 09/615,154, filed July 13, 2000; 10/017,472, filed December 7, 2001; and 10/378,590, filed March 3, 2003.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Reg. No. 45,104  
Attorney for Applicants

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Date: August 12, 2004

Form PTO-1449 (modified)

AUG 16 2004



## List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

INGN:105US

Serial No.

10/791,692

Applicant:

Sunil Chada *et al.*

Filing Date:

March 2, 2004

Group:

1645

## U.S. Patent Documents

*See Page 1*

## Foreign Patent Documents

*See Page 2*

## Other Art

*See Page 3*

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	2002/0091098	7-11-02	Fisher	514	44	11-21-01
	A2	2003/0066095	4/03/03	Baubet <i>et al.</i>	800	3	5/24/01
	A3	4,682,195	7-21-87	Yilmaz	357	23.4	9-30-85
	A4	4,683,202	7-28-87	Mullis	435	91	10-25-85
	A5	4,797,368	1-10-89	Carter <i>et al.</i>	435	320	3-15-85
	A6	5,139,941	8-18-92	Muzyczka <i>et al.</i>	435	172.3	10-25-91
	A7	5,399,363	3-21-95	Liversidge <i>et al.</i>	424	490	7-1-92
	A8	5,466,468	11-14-95	Schneider <i>et al.</i>	424	450	10-28-94
	A9	5,543,158	8-6-96	Gref <i>et al.</i>	424	501	7-23-93
	A10	5,633,016	5-27-97	Johnson	424	649	5-1-95
	A11	5,641,515	6-24-97	Ramtoola	424	189	6-7-95
	A12	5,643,761	7/1/97	Fisher <i>et al.</i>	435	91.1	10/27/93
	A13	5,645,897	7-8-97	Andra	427	526	1-18-95
	A14	5,705,629	1-6-98	Bhongle	536	25.34	10-20-95
	A15	5,710,137	1/20/98	Fisher	514	44	8/16/96
	A16	5,739,169	4-14-98	Ocain <i>et al.</i>	514	658	5-31-96
	A17	5,747,469	5-05-98	Roth <i>et al.</i>	514	44	4-25-94
	A18	5,798,339	8-25-98	Brandes	514	34	6-28-93
	A19	5,801,005	9-1-98	Cheever <i>et al.</i>	435	7.24	3-31-95
	A20	5,824,311	10-20-98	Greene <i>et al.</i>	424	138.1	11-30-94
	A21	5,824,348	10-20-98	Fujiu <i>et al.</i>	425	120	1-16-97
	A22	5,830,880	11-3-98	Sedlacek <i>et al.</i>	514	44	4-18-97
	A23	5,846,225	12-8-98	Rosengart <i>et al.</i>	604	115	2-19-97

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List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant: Sunil Chada <i>et al.</i>	
		Filing Date: March 2, 2004	Group: 1645
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 2</i>		Other Art <i>See Page 3</i>

### U.S. Patent Documents

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	A24	5,846,233	12-8-98	Lilley <i>et al.</i>	604	414	1-9-97
	A25	5,846,945	12-8-98	McCormick	514	44	6-7-95
	A26	6,069,134	5/30/00	Roth <i>et al.</i>	514	44	10/17/97
	A27	6,177,074	1-23-01	Glue <i>et al.</i>	424	85.7	3-30-99
	A28	6,204,022	3/20/01	Johnson <i>et al.</i>	435	69.51	10/20/97
	A29	6,207,145	3/27/01	Tovey	424	85.4	5/09/97
	A30	6,250,469	6/26/01	Kline	206	571	11/01/00
	A31	6,326,466	12/04/01	Bottaro and Petryshyn	530	324	7/29/97
	A32	6,331,525	12/18/01	Chiou and Carlo	514	44	8/23/99
	A33	6,342,379	1/29/02	Tsien and Gonzalez	435	173.4	12/13/99
	A34	6,348,352	2-19-02	Shepard <i>et al.</i>	435	455	12-04-95
	A35	6,350,589	2/26/02	Morris <i>et al.</i>	435	41	12/31/98
	A36	6,355,622	3/12/02	Fisher	514	44	2/16/99
	A37	6,372,218	4/16/02	Cummins	424	184.1	1/31/95
	A38	6,379,701	4/30/02	Tracy <i>et al.</i>	424	486	9/18/00

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Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	266032	5-4-88	Europe			
	B2	WO 95/11986	5-4-95	PCT			
	B3	WO 98/07408	2-26-98	PCT			
	B4	WO 98/28425	7-2-98	PCT			
	B5	WO 98/35554	8-20-98	PCT			

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### Foreign Patent Documents

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	B5	WO 00/05356	2-3-00	PCT			
	B6	WO 00/26368	5-11-00	PCT			
	B7	WO 00/71096	11-30-00	PCT			
	B8	WO 01/05437	2-25-01	PCT			

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Anderson, "Human gene therapy," <i>Nature</i> , 392:25-30, 1998.
	C2	Angiolillo <i>et al.</i> , "A role for the interferon-inducible protein 10 in inhibition of angiogenesis by interleukin-12," <i>Ann. NY Acad. Sci.</i> , 795:158-167, 1996.
	C3	Austin-Ward and Villaseca, "Gene therapy and its applications," abstract only, <i>Rev. Med. Chil.</i> , 126:838-845, 1998.
	C4	Balachandran <i>et al.</i> , "Activation of the dsRNA-dependent protein kinase, PKR, induces apoptosis through FADD-mediated death signaling," <i>EMBO J.</i> , 17(23):6888-6902, 1998.
	C5	Blumberg <i>et al.</i> , "Inyrtlrukin 20: discovery, receptor identification, and role in epidermal function," <i>Cell</i> 104:9-19, 2001.
	C6	Bonavida <i>et al.</i> , "Selectivity of TRAIL-mediated apoptosis of cancer cells and synergy with drugs: The trail to non-toxic cancer therapeutics," <i>Int J Oncol</i> , 15:793-802, 1999.
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	C8	Bowie <i>et al.</i> , "Deciphering the message in protein sequences: tolerance to amino acid substitutions," <i>Science</i> , 247(4948):1306-10, 1990.
	C9	Bukowski <i>et al.</i> , "Signal transducton abnormalities in T lymphocytes from patients with advanced renal carcinoma: Clinical relevance and effects of cytokine therapy," <i>Clin. Cancer Res.</i> , 4(10):2337-2347, 1998.

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Exam. Init.	Ref. Des.	Citation
	C10	Cao <i>et al.</i> , "Adenoviral transfer of mda-7 leads to BAX up-regulation and in mesothelioma cells, and is abrogated by over-expression of BCL-XL," <i>Molecular Medicine</i> , 8(12):869-876, 2002.
	C11	Caudell <i>et al.</i> , "The protein product of the tumor suppressor gene, melanoma differentiation-associated gene 7, exhibits immunostimulatory activity and is designated IL-24," <i>J. Immunol.</i> , 168:6041-6046, 2002.
	C12	Chen and Tan, "Inhibition of the c-Jun N-terminal kinase (JNK) signaling pathway by curcumin," <i>Oncogene</i> , 17:173-178, 1998.
	C13	Chinnaiyan <i>et al.</i> , "Combined effect of tumor necrosis factor-related apoptosis-inducing ligand and ionizing radiation in breast cancer therapy," <i>Proc Nat'l Acad Sci USA</i> . 97:1754-1759, 2000.
	C14	Christodoulides <i>et al.</i> , "Immunization with recombinant class 1 outer-membrane protein from <i>neisseria meningitidis</i> : influence of liposomes and adjuvants on antibody avidity, recognition of native protein and the induction of a bactericidal immune response against meningococci," <i>Microbiology</i> , 144(Pt 11):3027-3037, 1998.
	C15	Cross <i>et al.</i> , "A p53-dependent mouse spindle checkpoint," <i>Science</i> , 267:1353-1356, 1995.
	C16	Crystal, "Transfer of genes to humans: early lessons and obstacles to success," <i>Science</i> , 270:404-409, 1995.
	C17	Cuddihy <i>et al.</i> , "Double-stranded-RNA-activated protein kinase PKR enhances transcriptional activation by tumor suppressor p53," <i>Mol. Cell. Biol.</i> , 19(4):2475-2484, 1999.
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U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 2</i>	Other Art <i>See Page 3</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C22	Deonarian, "Ligand-targeted receptor-mediated vectors for gene delivery," <i>Exp. Opin. Ther. Patents</i> , 8(1):53-69, 1998.
	C23	Dragovich <i>et al.</i> , "Signal transduction pathways that regulate cell survival and cell death," <i>Oncogene</i> , 17:3207-3213, 1998
	C24	Dumoutier <i>et al.</i> , "Cutting edge: STAT activation by IL-19, IL-20 and mda-7 through IL-20 receptor complexes of two types," <i>J Immunol</i> , 167:3545-3549, 2001.
	C25	Dumoutier <i>et al.</i> , "Human interleukin-10-related T cell-derived inducible factor: molecular cloning and functional characterization as an hepatocyte-stimulating factor," <i>Proc. Natl. Acad. Sci. USA</i> . 97:10144-10149, 2000.
	C26	Eck and Wilson, "Gene-based therapy," <i>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</i> , McGraw-Hill, 77-101, 1996.
	C27	Ekmekekcioglu <i>et al.</i> , "Differential increase of Fas ligand expression on metastatic and thin or thick primary melanoma cells compared with interleukin-10," <i>Melanoma Research</i> 9:261-272, 1999.
	C28	Ekmekekcioglu <i>et al.</i> , "Down-regulated melanoma differentiation associated gene (MDA-7) expression in human melanomas," <i>Intl. J. Cancer.</i> , 94:54-59, 2001
	C29	Ekmekekcioglu <i>et al.</i> , "Negative association of melanoma differentiation-associated gene (mda-7) and inducible nitric oxide synthase (iNOS) in human melanoma: MDA-7 regulated iNOS expression in melanoma cells," <i>Mol. Cancer Therapeutics</i> , 2:9-17, 2003.
	C30	el-Kareh and Secomb, "Theoretical models for drug delivery to solid tumors," <i>Crit. Rev. Biomed. Eng.</i> , 25:503-571, 1997.
	C31	Ellerhorst <i>et al.</i> , "Loss of MDA-7 expression with progression of melanoma" <i>J Clin Oncol</i> , 20:1069-1074, 2002.
	C32	Erlandsson, "Molecular genetics of renal cell carcinoma," <i>Cancer Genet. Cytogenet</i> , 104:1-18, 1998.
	C33	Fathallah-Shaykh <i>et al.</i> , "Gene transfer of IFN- $\gamma$ established brain tumors represses growth by antiangiogenesis," <i>J. Immunol.</i> , 164:217-222, 2000.
	C34	Fickenscher <i>et al.</i> , "The interleukin-10 family of cytokines," <i>Trends Immunol</i> , 23: 89-96, 2002.

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U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 2</i>	Other Art <i>See Page 3</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C35	Frigerio <i>et al.</i> , "Analysis of 2166 clones from a human colorectal cancer cDNA by partial sequencing," <i>Human Molecular Genetics</i> , 4(1):37-43, 1995.
	C36	Fulci <i>et al.</i> , "p53 and brain tumors: from gene mutations to gene therapy," <i>Brain Pathol.</i> , 8(4):599-613, 1998.
	C37	Gallagher <i>et al.</i> , "Cloning, expression and initial characterisation of interleukin-19 (IL-19), a novel homologue of human interleukin-10 (IL-10)," <i>Genes Immun.</i> 1:442-450, 2000.
	C38	Gazdar and Minna, "Targeted therapies for killing tumor cells," <i>Proc. Natl. Acad. Sci., USA</i> , 98(18):10028-10030, 2001.
	C39	GenBank Accession Number XM_001405
	C40	Gertig and Hunter, "Genes and environment in the etiology of colorectal cancer," <i>Semin. Cancer Biol.</i> , 8(4):285-298, 1997.
	C41	Gil <i>et al.</i> , "Induction of apoptosis by double-stranded-RNA-dependent protein kinase (PKR) involves the $\alpha$ subunit of eukaryotic translation initiation factor 2 and NF- $\kappa$ B," <i>Molecular and Cellular Biology</i> , 19(7):4653-4663, 1999.
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	C43	Goh <i>et al.</i> , "The protein kinase PKR is required for p38 MAPK activation and the innate immune response to bacterial endotoxin," <i>EMBO J.</i> , 19(16):4292-4297, 2000.
	C44	Górecki, "Prospects and problems of gene therapy: an update," <i>Expert Opin. Emerging Drugs</i> , 6(2):187-198, 2001.
	C45	Haines <i>et al.</i> , "Expression of PKR (p68) recognized by the monoclonal antibody TJ4C4 in human lung neoplasms," <i>Virchows Arch. B. Cell Pathol.</i> , 62:151-158, 1992.
	C46	Han <i>et al.</i> , "The E1B 19K protein blocks apoptosis by interacting with and inhibiting the p53-unducible and death-promoting Bax protein," <i>Genes Dev.</i> , 10(4):461-477, 1996.
	C47	Hanibuchi <i>et al.</i> , "Therapeutic efficacy of mouse-human chimeric anti-ganglioside gm2 monoclonal antibody against multiple organ micrometastases of human lung cancer in NK cell-depleted scid mice," <i>Int. J. Cancer</i> , 78:480-485, 1998.
	C48	Hartmann <i>et al.</i> , "High frequency of p53 gene mutations in primary breast cancers in Japanese women, a low-incidence population," <i>Br. J. Cancer</i> , 73(8):896-901, 1996.

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Exam. Init.	Ref. Des.	Citation
	C49	Hartmann <i>et al.</i> , "Overexpression and mutations of p53 in metastatic malignant melanomas," <i>Int. J. Cancer</i> , 67(3):313-317, 1996.
	C50	Hellstrand <i>et al.</i> , "Histamine and cytokine therapy," <i>Acta. Oncol.</i> , 37:347-353, 1998.
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